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| APPLICATION NO.                       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|---------------------------------------|-------------|----------------------|--------------------------|------------------|
| 10/049,562                            | 07/08/2002  | Charles V Clevenger  | PENN-0798                | 7451             |
| 7590 10/20/2004                       |             |                      | EXAMINER                 |                  |
| Licata & Tyrr                         |             |                      | CROUCH, DEBORAH          |                  |
| 66 East Main Street Marlton, NJ 08053 |             |                      | ART UNIT PAPER NUMBER    |                  |
|                                       |             |                      | 1632                     |                  |
|                                       |             |                      | DATE MAIL ED: 10/20/2004 | 1                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)                    |  |  |  |
|--|---|---------------------------------|--|--|--|
|  | 10/049,562  | CLEVENGER ET AL.                |  |  |  |
| Office Action Summary  | Examiner  | Art Unit                        |  |  |  |
|  | Deborah Crouch, Ph.D.                                   | 1632                            |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |                                 |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                                 |  |  |  |
| Status   |   |                                 |  |  |  |
| 1) Responsive to communication(s) filed on   |   |                                 |  |  |  |
|  | -<br>action is non-final.                               | /                               |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |   |                                 |  |  |  |
| Disposition of Claims  |   |                                 |  |  |  |
| <ul> <li>4)  Claim(s) 1-10 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) is/are rejected.</li> <li>7)  Claim(s) _ is/are objected to.</li> <li>8)  Claim(s) _ 1-10 are subject to restriction and/or election requirement.</li> </ul>   |   |                                 |  |  |  |
| Application Papers   |   |                                 |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |                                 |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |   |                                 |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |                                 |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |                                 |  |  |  |
| Priority under 35 U.S.C. § 119   |   |                                 |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |                                 |  |  |  |
| Attachment(s)  |   |                                 |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary (                                  | PTO-413)                        |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date   | Paper No(s)/Mail Dat 5) Notice of Informal Pa 6) Other: | e<br>tent Application (PTO-152) |  |  |  |

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1, 3 and 4, drawn to a composition for modulating a somatolactogenic function comprising cyclophilin B and a method for modulating somatolactogenic function comprising administering cyclophilin B.
- II. Claims 1-3, 5 and 6, drawn to a composition for modulating a somatolactogenic function comprising a mutant of cyclophilin B and a method for modulating somatolactogenic function comprising administering a mutant of cyclophilin B.
- III. Claims 1, 3 and 5, drawn to a composition for modulating a somatolactogenic function comprising an inhibitor of the interaction of cyclophilin B with a somatolactogenic hormone and a method for modulating somatolactogenic function comprising administering the inhibitor.
- IV. Claims 7 and 8, drawn to a method for identifying test compounds as inhibitors of somatolactogenic functions comprising assessing the ability of a test compound to inhibit the interaction of cyclophilin B with a somatolactogenic hormone.
- V. Claims 9 and 10, drawn to a method for diagnosing diseases associated with abnormal somatolactogenic functions comprising obtaining a biological sample, and comparing cyclophilin B levels in the patient with cyclophilin B levels of a normal individual.

37 CFR 1.475 (b) states:

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An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product;
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0408. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah Crouch, Ph.D. Primary Examiner Art Unit 1632

October 18, 2004